Stem cells, morals and the courts

Earlier this year, the Court of Justice of the European Union, in *Oliver Brüstle v Greenpeace e.V.*, cast a decision that has wide-ranging implications for research on human embryonic stem cells and subsequent commercial development. The court revoked a patent previously granted to German stem cell researcher Oliver Brüstle for a method to generate nerve cells from human embryonic stem cells. The court's argument is complex: first, a method to manipulate human embryonic stem cells for research involves the destruction of a human embryo—it does not matter that this happened in the past—and, second, a patent is commercial in nature: thus, the patent cannot be issued because it involves the destruction of a human embryo for commercial or industrial purposes even if these are hypothetical. The decision by the European judges brings into focus a number of societal and governance issues with respect to stem cell research and its applications that have been discussed extensively, but that are only beginning to be resolved.

The use of morality or *ordre public* (public policy) tests for the acceptability of patents is a critical issue for Europe. Indeed, Greenpeace invoked concerns about commodification—turning something that is not regarded as a commercial product into a product—as the main argument for their challenge to Brüstle's patent (see the comment by Caulfield & Ogbogu, page 12). It remains unclear whether commodification and dignity concerns will be limited to stem cells or expanded to include any uses of human tissue; for the moment scientists and policymakers do not know the limit of the commodification argument.

The decision in Brüstle that conflates scientific research with a commercial motivation is particularly difficult to resolve as it essentially limits the freedom of research. The concepts of scientific and

academic freedoms are of great importance in open societies, and in some countries, such as Germany, these freedoms are recognized as constitutional rights. The problem is that academic freedom is not a blanket permission to use any and all means to investigate any vaguely interesting problem. The experimental approaches used for research are subject to limits. For example, the use of human subjects and animals in research are areas that might be legitimately restricted. Certain types of research, such as experiments using smallpox, ebola or Spanish flu viruses are considered too dangerous for society to be routinely approved, but this does not prohibit the work, it only sets limits on who is allowed to do it. But for now, there are few if any restrictions on the questions that scientists might ask; for the most part, they only need to balance the risks inherent in their experimental protocols—risks to humans or animals, risks to the environment or, in some cases, non-physical risks such as to community values—with the value of their research.

Human stem cell research certainly requires oversight, and potentially some restrictions. Right now, the problem is that the science has gotten ahead of the policy in most countries. The original Brüstle patent was filed in 1997, even before the publications by James Thomson and John Gearhart that described the generation of human embryonic stem cell lines in 1998. The policy and ethics communities had been somewhat slow in dealing with the ethical and moral questions invoked by human stem cell research: there were no rigorous policy studies completed before the 1998 papers even though scientists had started exploring applications by the mid-1980s. Since then, many organizations representing or concerned about scientists and science have conducted studies; national bioethics commissions have looked at the problems; both

scientists and the public have been involved in moving the conversations forward.

How these conversations will eventually turn into policy, potentially including regulation, remains an open question. Guidance and regulation, where necessary, arrived at through public discussions including scientists, are necessary and a standard for regulating scientific research. The courts, the patent systems and even legal challenges to patents are nonetheless important to interpret and shift the boundaries between permissible and unacceptable research. However, a model of oversight that depends largely on legal challenges years after scientists have generated applications creates uncertainty to those who want to do the research and to the public that funds this research.

Patents are frequently disputed on technical issues; it might simply become more common that patents are challenged based on arguments about morality, commodification and *ordre public*. Undoubtedly, this will result in a more unpredictable situation for scientists. Ideally, concerns about the morality of a technology would be resolved before patents are issued, let alone before the technology is regulated one way or the other. But, given the diverse societies we live in and the ways that moral views change over time, legal challenges to research and patents might need to be accepted as one of the prices of conducting responsible research. What remains to be determined is whether or not limits or regulations on controversial research, including stem cell research, is preferable to downstream legal challenges.

Michele Garfinkel is the Manager of the EMBO Science Policy Programme. The editorial represents her personal opinions and not those of EMBO.

EMBO reports (2012) 13, 2; published online 2 December 2011;
doi:10.1038/embor.2011.242